July 22, 1992

SCIENCE ADVISORY BOARD REVIEW OF THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY'S DRAFT RISK ASSESSMENT OF ETS.

At the end of a public hearing held in Washington over the last two days, the Sciene Advisory Board (Indoor Air Quality and Total Human Exposure Committee) of the United States Environmental Protection Agency (SAB) gave the impression that the EPA's Draft Risk assessment on ETS was imperfect in many respects, but that the general claim of classification as a known human carcinogen (Group A) was justified based on the general weight of evidence. There was also general consensus on the conclusions reached by the EPA regarding alleged effects of ETS on children.

The SAB will, over the next month or so, produce a consensus report on their findings, which will probably be presented at a meeting of the Executive Committee of the SAB in late October (anticipated to be held on October 27 or 28). The Executive Committee's recommendations are likely to be forwarded to the Administrator of EPA in November, and, after EPA have completed the revisions suggested by the SAB, the risk assessment would probably be officially released in early 1993.

The SAB suggested that, even though it is likely to recommend that major sections of the document are rewritten, no further public review of the document would be necessary.

Although there is no certainty as to what the SAB report may contain, the following points are anticipated from the discussions that took place in the public hearing.

1. The SAB concludes that EPA have made a sufficient case to classify ETS as a Group A known human carcinogen.

2. This classification cannot be based solely on comparisons between mainstream and ETS. The EPA draft did not demonstrate sufficient similarity to allow use of the epidemiologic database on mainstream smoke. It will be suggested, though, that the presence of similar compounds in MS and ETS add some weight to the overall classification of ETS.

3. That the epidemiologic database is, with the inclusion of the Fontham study, consistent with a conclusion of a causal

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relationship between ETS exposure and lung cancer, and that no confounding factor or bias had been identified that would explain the elevated risks observed in many of the studies.

4. That, however, the conclusion of a causal relationship cannot be based on the ETS epidemiology alone, but on the combination of this data with all other evidence.

5. That the quantitative risk assessment of ETS is valid, but should exclude consideration of former smokers and should include a proper consideration of uncertainty. (The net effect will probably be a reduced "best estimate" of estimated annual mortality of lung cancer due to ETS exposure (probably to around 2000 per year) with either a wider range of uncertainty or with no range.)

6. The SAB will most probably concur with all of the EPA's conclusions on the respiratory effects of ETS on children.

7. The estimates of numbers of children affected by ETS may be approved or it may be recommended that for some effects these numbers are increased.

8. Discussion of Sudden Infant Death Syndrome will be removed from the section quantifying risk, but remain in the chapter identifying potential risk.

9. The SAB may recommend that the document, and particularly the summary and conclusions, be written in a manner such that bias or preconceptions of the Agency are not obvious.

10. The recommendation will be that this document is close enough to completion to preclude further public comment.

A full transcript of the public meeting should be available in around a week. The report of the SAB is not expected before September.

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